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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,844	02/11/2004	Lon J. Wilson	1789-12301	3026

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,844	WILSON ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-22 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,23,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending in the application. Claims 11-22 and 24-26 are withdrawn from consideration. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

NOTE: The benefit of priority to provisional application 60/356,856 is not granted to the instant claims as the provisional application 60/356,856 does not describe functionalization of fullerenes with antibiotics, especially vancomycin as stated in the office action mailed 3/23/07.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the range of two to eight linking molecules although it does state that up to 8 malonate groups can be placed on C_{60}.

3. Claims 1-10,23,27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what linking molecules would be acceptable as the specification only provides for malonate or serinol, etc. It is not clear as to what substituents, functional groups, properties, etc are required by the linker to be acceptable for the instant invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what type of targeting agent is desired by the applicant as both Markush language and the term comprising (open language) are used within the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-10,23,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wilson et al. (US 6,660,248B2) in view of the combination of Yan et al. (US 5,830,539) and Stahl et al. (US 5,470,843) and further view of Lei et al. (US 6,777,445B2).

7. Wilson et al. (US 6,660,248B2) discloses a fullerene scaffold having an amide linker containing two therapeutic/diagnostic agents (on one linker), water-solubility enhancing molecules and tissue-targeting entities (fig.7; column 3, lines 58-59; column 60, lines 60-61). C_{60} fullerene scaffolds are used for their low toxicity, reduced viscosity and large surface area/aromatic structure which allows for attachment of additional moieties (column 4, lines 13-22). Wilson et al. does not disclose an antibiotic (i.e. penicillin) as the therapeutic agent or that the targeting agents may be diphosphonates.

8. Yan et al. (US 5,830,539) discloses coating/functionalizing substrates, such as fullerenes with a first layer/linker comprising a molecular tether covalently bonded to the surface and a second layer comprising therapeutic agents, diagnostic agents, antibodies, etc. bonded to the first layer (abstract; column 3, lines 9-12; column 4, lines 12-37). The functionalized fullerenes may be converted into devices having further functional groups attached to the first layer, such as targeting ligands (i.e. antigens), antibiotics, etc. (column 6, lines 45-49; column 7, lines 60-63).

9. Stahl et al. (US 5,470,843) discloses a composition comprising a carbohydrate-linker-polymer/potentiator unit. The hydrophilic polymer portion may consist of a hydrophobic fullerene/potentiator unit (column 1, lines 50,57-59 and 61-64; column 6, line 57; column 13, lines 1 and 6; column 14, lines 19-23) and be bound to the carbohydrate via a linker (spacer) (column 7, lines 24-25; column 11, lines 39-41). The compounds of the disclosure may also be coupled/bound to a drug moiety, such as antibiotics/penicillins, erythromycins, etc. (column 14, lines 43-46 and 58+). The role of the potentiator is to improve the affinity of the receptor-binding portion of the molecule

or improve the electrostatic interaction of the composition with its cognate receptor and is thus a targeting agent. Also the potentiator improves the overall reactivity of the compound in aqueous solution (column 4, lines 43-52; column 13, lines 6-13 and 20-23). The pharmaceutical compositions/aerosols of the disclosure are suited for the prophylaxis and/or therapy of bacterial and viral infections and of diseases which involve inflammatory processes (column 19, lines 22-27 and 45).

10. Lei et al. (US 6,777,445B2) discloses a water-soluble fullerene (C_{60}) derivative to treat bacterial or viral infections, such as *E. coli, Staphylococcus aureus*, etc (column 2, lines 7-14; column 3, lines 8-20; column 4, lines 10 and 18). Administration of a pharmaceutical formulation of the fullerene to a patient may include lubricating agents, carriers or may be made into aerosols (column 6, particularly line 48). The fullerene described contains multiple PO_3H, SO_3H, and CO_2H substituents that allows for bone-targeting bound to the fullerene molecules (column 5, lines 7-8).

11. At the time of the invention it would have been obvious to one ordinarily skilled in the art to attach multiple therapeutic agents for the treatment of viral infections, such as antibiotics to a fullerene molecule via a linking molecule (combination of Wilson et al. and Yan et al.). The linking of antibiotics to fullerene is would give predictable results as the devices of Yan et al. are comprised of fullerenes. The substitution of one antibiotic for anther would be obvious as they are utilized for the treatment of viral infections. The use of the targeting ligands of Lei et al. with the functionalized fullerenes of the combined disclosures would be obvious and predictable as the disclosures of Wilson et al. and Lei et al. are drawn to the same products (i.e. targeted fullerenes).

Conclusion

No claims are allowed at this time.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
October 12, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER